

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
10 June 2004 (10.06.2004)

PCT

(10) International Publication Number
WO 2004/048600 A3

- (51) International Patent Classification⁷: **G01N 33/53**
- (21) International Application Number:
PCT/US2003/037749
- (22) International Filing Date:
24 November 2003 (24.11.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/428,521 22 November 2002 (22.11.2002) US
- (71) Applicant (for all designated States except US): **EMORY UNIVERSITY** [US/US]; Office of Technology Transfer, 1784 North Decatur Road, 1st Floor, North Decatur Building, Suite 130, Atlanta, GA 30322 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **GEWIRTZ, Andrew** [US/US]; 2630 Harrington Drive, Decatur, GA 30033 (US). **SITARAMAN, Shanti, V.** [US/US]; 1951 Grace Arbor Court, Atlanta, GA 30329 (US). **KAPPROTH, Jan, Michael** [US/US]; 2344 Briarcliff Crossing, Atlanta, GA 30345 (US).
- (74) Agent: **LINDER, Christopher, B.**; Thomas, Kayden, Horstemeyer & Risley, LLP, 100 Galleria Parkway, NW, Suite 1750, Atlanta, GA 30339-5948 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:
— with international search report
- (88) Date of publication of the international search report:
7 October 2004
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 2004/048600 A3

(54) Title: **DIAGNOSTIC TESTS AND METHODS FOR DIAGNOSING INFLAMMATORY BOWEL DISEASE**

(57) Abstract: Methods are disclosed for diagnosing inflammatory bowel disease (IBD), one exemplar method of which includes determining whether a sample is positive for anti-flagellin antibodies (AFA), diagnosing the presence of IBD when the sample is positive for AFA, and diagnosing the absence of IBD when the sample is negative for AFA. Alternatively, instead of testing for positivity with respect to AFA, or in addition thereto, an exemplar method can determine whether the sample has an AFA level above an AFA cut-off value (X); and diagnosing IBD when the AFA level is above X, and diagnosing absence of IBD when the AFA level is below X. Test kits that include items used to carry out the disclosed methods are also disclosed.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/37749

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G01N 33/53

US CL : 435/7.92

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : Please See Continuation Sheet

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,292,667 A (PODOLSKY et al) 08 March 1994 (08.03.1994), see entire document.	1-22

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

14 March 2004 (14.03.2004)

Date of mailing of the international search report

07 JUL 2004

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Chris L. Chin

Telephone No. 571-272-1600

INTERNATIONAL SEARCH REPORT

PCT/US03/37749

Continuation of B. FIELDS SEARCHED Item 1:

435/7.3, 7.92, 7.93, 7.94, 975; 436/172, 516, 518, 528, 804, 805

Continuation of B. FIELDS SEARCHED Item 3:

EAST, CAS, BIOSIS, MEDLINE, USPATFULL

search terms - inflammatory bowel disease, flagellin, anti-flagellin, antibodies, enzyme, ELISA, immunoassay